

## REMARKS

This is a full and timely response to the Official Action mailed March 27, 2008. It is timely in view of the Petition for Extension of Time filed concurrently herewith (September 27, 2008 being a Saturday). A Notice of Appeal is being filed concurrently herewith. Reexamination and reconsideration of the rejections set forth therein in light of the following remarks and the Declarations of Connie Baozhen Lin and Miri Seiberg are courteously requested. Entry is respectfully requested as this Amendment is believed to place the claims in better form for allowance or appeal. Claims 15, 16, 18-22 and 30-34 are pending.

Claims 15, 16 and 18-22 have been amended by adding the clause “having trypsin inhibitory activity”. This amendment finds basis in the original Specification at p. 7, l. 12-14.

The Office Action of March 27, 2008 rejected claims 22 and 34 under 35 U.S.C. 102(a) as being anticipated by WO 99/36050 (“Kelly et al.”). Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

The Office Action states that Kelly et al. teach:

...using soy extract for protecting skin from UV damage (abstract). The soy extract of Kelly et al. is obtained by the extraction with a mixture of organic solvents and water. The recitation of “non-denatured” soy product is inherent in the reference because soy beans are extracted without using enzymes and/or temperature. The compositions of Kelly et al. may also contain preservatives...Examiner notes that Kelly et al. teach that the ratio of organic solvent in water may be as low as 0.5%. It is highly unlikely that 0.1% of ethanol in water will cause protein denaturing. Moreover, the soy extract containing compositions herein possess the same skin protecting or trypsin inhibitory activity as claimed because a composition and its properties are inherent. Applicant has not differentiated between soy beans that have or do not have this property by their structure or process steps. [Office Action, p. 3, 4]

Applicants respectfully submit that Kelly et al. does *not* anticipate the limitations of independent claims 22 and 34 as set forth in the Office Action. Applicants therefore respectfully request reconsideration of the foregoing rejection in view of the ensuing discussion and the Declarations of Miri Seiberg, Ph. D. [“Seiberg Declaration”] and Connie Baozhen Lin [“Lin Declaration”] submitted concurrently herewith.

Kelly et al. is principally directed to the use of isoflavones to achieve the results touted therein. Nowhere does Kelly et al. describe explicitly or suggest non-denatured soy extracts containing soy trypsin inhibitory (“STI”) activity as being useful in topical compositions. While the Office Action indicates that neither Kelly et al. nor the WO 93/23069 publication mention “denatured” soybean extract, the only way in which to understand whether or not the extracts

described therein have denatured proteins would be to review the process by which such extracts are derived.

The *only* method described for preparing extracts in Kelly et al. is that set forth in the WO93/23069 publication. This publication clearly relates to extracts that must be suitable for oral administration [WO93/23069...], notwithstanding the reference to the ratio of solvent in water possibly being 0.1%. Kelly et al. also clearly indicates that the compositions described therein are intended for topical “*or for oral administration* prior to or following UV exposure...” [Kelly et al., p. 3, l. 27] (emphasis added). The Kelly et al. publication further states clearly that the preferred ratio of solvent to water should be 40% to 60% [Kelly et al., p. 11, l. 27].

Applicants respectfully point out that the soy extract of Kelly et al. would *not* contain STI. As set forth in the accompanying Seiberg Declaration, soybean extract (recited by Kelly et al.) obtained by extraction with a mixture of organic solvents and water will not contain STI. As it is water-soluble, STI would be highly unlikely to enter the organic phase. Kelly removes all **but** the organic phase during the extraction process. As the Kelly et al. preparation process requires removal of the aqueous phase, the STI would be removed along with the aqueous phase and would not be present in the resulting material. STI will be retained in the aqueous phase, which is removed by the Kelly procedure, or will be denatured if found in traces in the organic phase.

Even if STI **were** present in the organic phase, it would be denatured by the presence of organic solvents, as set forth in the accompanying Seiberg Declaration [Seiberg Declaration, ¶3].

Moreover, applicants respectfully note that the term “non-denatured” is descriptive of the *product* claimed in the above-captioned patent application rather than referring to the process by which the compositions are made. As set forth above and indicated in the Lin Declaration, applicants respectfully submit that the compositions of Kelly et al. and those of applicants’ claims are quite different.

Merely because the compositions of Kelly et al. and those of applicants are derived from soybeans does not imply that they are similar. There are many constituent compounds in soybeans. The beans may be treated in order to inactivate certain compounds and some compounds may be extracted in order to isolate them from the beans. As set forth in the accompanying Lin Declaration, it can be seen that the behavior of soybean extracts containing isoflavones, such as those exemplified in Kelly et al. is different from the behavior of soybean extracts containing soybean trypsin inhibitory activity. (Lin Declaration, ¶¶7, 8, 10). Thus, the

compositions taught in Kelly et al. would not have led one of ordinary skill in the art to the nondenatured compositions of applicants' invention.

Furthermore, the term "nondenatured" does not describe particular types of soybeans. All soybeans in their natural state are nondenatured as they have not been acted upon. Rather, it describes to the compositions useful in the methods of applicants' invention in which certain protein activities have *not* been rendered denatured or extracted out of the composition prior to use.

Accordingly, Kelly et al. does not disclose, teach or suggest the claimed limitations of independent claims 22 and 34. At least in view of the foregoing, claims 22 and 34 are allowable. Withdrawal of the 102(a) rejection is respectfully requested.

The Office Action of March 27, 2008 rejected claims 15-16, 18-21, 30-33 under 35 U.S.C. 103(a) as being obvious over JP 5-320061 to Tokuyama in view of JP 62-36304 to Mizue. Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

The Office Action indicates that Tokuyama teaches "using aqueous or organic extract of soy beans and/or other legumes in unaltered form in topical compositions.... chapping skin, eczema, dermatitis, etc. [Office Action, p. 6]. The Office Action further indicates that Mizue teaches "stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA." [Office Action, p. 8]. The Office Action asserts that the Tokuyama reference teaches the same extraction method as disclosed in the instant application and therefore the soy product of Tokuyama is inherently non-denatured and possesses trypsin inhibitory activity. Applicants respectfully request reconsideration of the foregoing rejection in view of the ensuing discussion.

Applicants respectfully submit that Tokuyama or Mizue either individually or in combination do not teach or suggest the limitations of independent claims 15-16, 18-21, 30-33 as alleged in the Office Action. Tokuyama indicates a preference to utilize organic extracts, acidic or alkaline environment, and heating soybeans to obtain the soy extract described therein. Further, Tokuyama's preferred extraction methods are boiling (p. 3), pretreatment with an acid or alkali (p. 4) and processed in an organic solvent extraction (p. 4), all of which will denature STI. As set forth in the Seiberg Declaration, the extraction

methods used by Tokuyama will not result in compositions having STI activity. [Seiberg Declaration, ¶3]

Nor does Mizue compensate for the inadequacies of Tokuyama in directing those of ordinary skill in the art toward applicants' claimed invention. The Office Action relied on Mizue to teach stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA. [Office Action, p. 8] The Office Action then concluded that it would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the cosmetic or dermatological soy extract-containing compositions of Tokuyama to add chemical agents such as preservatives. Adding preservatives to a composition that does not contain soy trypsin inhibitory activity, or which contains denatured proteins, will *not* resurrect the activity of the proteins that originally had such soy trypsin activity.

Accordingly, Tokuyama and Mizue do not disclose, teach or suggest the claimed limitations of independent claims 15-16, 18-21, 30-33. Applicants respectfully request reconsideration of the foregoing rejection under 35 U.S.C. §103(a).

For the foregoing reasons, applicants respectfully submit that the above-captioned application is now clearly in condition for allowance. Accordingly, favorable reconsideration of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750.

Respectfully submitted,

/Andrea L. Colby/

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